

Application No.: 10/018,470

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REMARKS**I. Status of the Claims**

With this amendment, claims 1 and 2 are pending in the present application and under examination. Claims 3-21 and 24-82 are withdrawn. Claims 22-23 are canceled.

II. Withdrawal of Rejections

Applicants thank the Examiner for withdrawing the rejection of claims 1-2 under 35 U.S.C. § 101 and § 102(b).

III. Rejections under 35 U.S.C. § 103

Claims 1-2 have been rejected under 35 §103(a) as being unpatentable over Ribot et al. The Examiner admits that Ribot fails to teach all of the limitations of the claimed invention, but asserts that the differences between Ribot et al. should not be given any patentable weight. Applicant respectfully traverses this rejection and its supporting remarks.

Specifically, the Examiner has asserted that the difference between the claimed invention and Ribot et al. "constitutes non-functional descriptive material because the content of the nucleic acid sequence database does not alter how the computer system functions, i.e., the database of the claimed computer system does not reconfigure the computer system to perform a different function than the computer system of Ribot et al."

As part of the burden to establish a *prima facie* case of obviousness on the grounds that claimed printed matter lacks patentable weight, the PTO must establish the absence of a novel, nonobvious functional relationship between the printed matter and the rest of the claimed invention. *See In re Lowry*, 32 U.S.P.Q.2d 1031, 1034 (Fed. Cir. 1994). In making his rejection, the Examiner only cites four cases referenced in MPEP §2106.01 relating to utility rejections for computer-related inventions, none of which support this assertion.

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First, the Examiner cites *In re Gulack*, a case relating to a mathematical educating device in the form of a band or ring, for its assertion that printed matter which is not functionally related to substrate will not distinguish the invention from the prior art. However, the Examiner fails to provide any reasons why *Gulack* supports his argument that the sequence in a database is not functional. The SEQ ID NO:1 of the claimed invention is an important functional element that substantially alters the result of the method. SEQ ID NO:1 is 2,242,716 basepairs in size, spanning the entire genome of the organism and therefore should yield at least a couple of thousand amino acid sequences (called open reading frames or ORFs in the art). In contrast the longest sequence of Ribot *et al.* is a mere 5,416 basepairs and Ribot *et al.* only identify four ORFs in this. Thus, the differences in the element are nearly three orders of magnitude and similarly, the results produced are also nearly three orders of magnitude in difference. Further each ORF corresponds to a unique protein that is likely produced by the bacteria which performs a novel function and thus each amino acid sequence (or ORF) will be different.

Second, the Examiner cites *In re Ngai* for not giving patentable weight over the prior art to an identical process of amplifying ribonucleic acids with a distinct set of printed instructions. In this case, the Federal Circuit distinguished the invention from those where printed matter and structure were interrelated, stating "here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All the kit does is teach a new use for an existing product." In contrast, Applicant has provided an invention where the "printed matter" and the method are inseparable and thus the case is inapplicable. In the instant invention, the sequence in the database is not merely a set of instructions regarding how to use the invention. The instant invention is a method for searching SEQ ID NO: 1 which enables identification of all possible ORFs in the *Neisseria meningitidis* genome encoding amino acids sequences potentially useful as antigens for a meningitis vaccine and many other utilities. If Applicant's method did not scan SEQ ID NO:1, it could not accomplish this result and thus the printed matter and method are interrelated to an extent that the printed matter has patentable weight.

Third, the Examiner cites to *In re Lowry* for distinguishing functional data structure and computer memory from nonfunctional printed matter. The Examiner is respectfully reminded that

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similarity to the invention of *Lowry* is not an exclusive test for the patentable weight of data in a database. However, the presently pending claims are a perfect example of the functionality as required in *Lowry*. As discussed above, the SEQ ID NO:1 is an important functional element because it dramatically expands the scope of the result beyond that taught in Ribot *et al.*

Finally, the Examiner cites to *Diehr* for ruling analogously as the previous three cases with regards to the standards for patentability of mathematical equations. While the Court in *Diehr* was looking at patentability, *Diehr* again supports the importance of the SEQ ID NO:1 element by focusing on the "transforming or reducing an article to a different state or thing." In this case, the different states or things are the identified amino acid sequences, which are much broader

In all of the cited cases, the distinguishing point seems to be whether the matter is merely "descriptive" or "functional." With the pending claims, SEQ ID NO:1 is the entire genome of the bacteria, which substantially alters and expands the degree and number of results producing many likely novel amino acid sequences that have not been previously identified. It is noteworthy that the output of the claimed method is an "identified amino acid sequence," which is, as discussed, substantially altered by use of SEQ ID NO:1.

Even if the Examiner had successfully made a *prima facie* case for the lack of patentable weight of the content of the database (which is traversed), the case is easily rebutted. In addition to its teachings regarding the standard for determining patentability of printed matter, *Gulack* also emphasized that the differences between the invention and the prior art cited against it cannot be ignored merely because those differences reside the content of the printed matter; the claim must be read as a whole. Applicants respectfully submit that when claims 1 and 2 are read as a whole, the content of the sequence in the database is clearly a patentable difference. As discussed above, SEQ ID NO: 1 is a 2,242,716 basepair sequence that was generated by sequencing the full genome of *Neisseria meningitidis*, serogroup B. The sequence listing of Ribot contains fifteen sequences with the longest nucleic acid sequence being a mere 5,416 base pairs. Thus SEQ ID NO: 1 is a novel sequence, not disclosed by Ribot, which contains multiple ORFs which have never been identified. Therefore, by virtue of "searching for putative open reading frames ... within a computer database

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containing SEQ ID NO: 1," the claimed invention reconfigures the computer system such that it is useful for identifying all possible ORFs in the *Neisseria meningitidis* genome encoding amino acid sequences potentially useful as antigens for a meningitis vaccine, rather than just a handful of ORFs.

Thus, the Examiner has failed establish a *prima facie* case that content of the sequence in the database lacks patentable weight. As the requirement that a *prima facie* case for obviousness establish that a reference or references combined must teach or suggest all of the limitations of the art was not disturbed by the recent Supreme Court *KSR Int'l Co. v Teleflex, Inc.* decision and as admitted by the Examiner, Ribot lacks this feature, Applicant therefore respectfully submits that the Examiner has failed to make a *prima facie* case for obviousness. Withdrawal of the rejection is thus respectfully requested.

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IV. Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 223002100400. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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